Claims of Brauker Ser. No. 11/334,876:	**Claims of** Say *et al.* Application Ser. No. 10/783,675	**Support in the** Say *et al.* Application Ser. No. 10/783,675
1. (Canceled).		
2. A computer system suitable for processing analyte data, the computer system comprising:	41. A computer system suitable for processing analyte data, the computer system comprising:	(Preamble) The present invention relates to devices and methods for the in vivo monitoring of an analyte using an electrochemical sensor to provide information to a patient about the level of the analyte (Field of Invention)
a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	The on-skin sensor control unit 44 also typically includes at least a portion of the electronic components that operate the sensor 42 and the analyte monitoring device system 40. One embodiment of the electronics in the on-skin control unit 44 is illustrated as a block diagram in FIG. 18A. The electronic components of the on-skin sensor control unit 44 typically include a power supply 95 for operating the on-skin control unit 44 and the sensor 42, **a sensor circuit 97 for obtaining signals from and operating the sensor 42**, a measurement circuit 96 that converts sensor signals to a desired format, and **a processing circuit 109 that, at minimum, obtains signals from the sensor circuit 97** and/or measurement circuit 96 and provides the signals to an optional transmitter 98. (Col. 36, ll. 41-60).

		The processing circuit 109 may have one or more of the following functions: 5) determine a level of an analyte in the interstitial fluid, 6) determine a level of an analyte in the bloodstream based on the sensor signals obtained from interstitial fluid, **7) determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values**, (Col. 39-40, ll. 61-62 and 5-10). Additionally: Typically, **data is transmitted to the receiver/display unit 46, 48 at least every hour, preferably, at least every fifteen minutes, more preferably, at least every five minutes, and most preferably, at least every one minute**. (Col. 43, ll. 9-12).
a processor module configured to determine a rate of change of the data stream; and	a processor module configured to determine a rate of change of the data stream; and	**The processing circuit 109 may have one or more of the following functions: 7) determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values**, (Col. 39-40, ll. 61-62 and 5-10).
a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point,	a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point,	In some embodiments, the analyte monitoring system 40 **includes two or more working electrodes 58 distributed over one or more sensors 42**. These working electrodes 58 may be used for quality control purposes. For example, the

		output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance. (Col. 39, ll. 9-16). One embodiment is a method of calibrating an electrochemical sensor having one or more working electrodes implanted in a patient. **A signal is generated from each of the working electrodes.** Several conditions are tested to determine if calibration is appropriate. (Col. 3, ll. 28-32). In another embodiment, calibration data may be obtained in a variety of ways. For instance, the calibration data may simply be factory-determined calibration measurements which can be input into the on-skin sensor control unit 44 using the receiver 99 or may alternatively be stored in a calibration data storage unit 100 within the on-skin sensor control unit 44 itself (in which case a receiver 99 may not be needed). The calibration data storage unit 100 may be, for example, a readable or readable/writeable memory circuit. Alternative or additional calibration data may be provided based on tests performed by a doctor or some other professional or by the patient himself. For example, **it is common for diabetic individuals to determine their own blood glucose concentration using commercially available**

		testing kits. The results of this test is input into the on-skin sensor control unit 44 either directly. (Col. 43, ll. 36-48).
wherein the reference input module is configured to reject a reference data point obtained when the rate of change of the data stream is above a threshold.	wherein the reference input module is configured to reject a reference data point obtained when the rate of change of the data stream is above a threshold.	These working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** If the output signals do not agree, then the patient may be alerted to replace the sensor or sensors. The comparison of the two signals may be made for each measurement or at regular intervals. Alternatively or additionally, the comparison may be initiated by the patient or another person. Moreover, the signals from both sensors may be used to generate data or **one signal may be discarded after the comparison.** (Col. 39, ll. 11-25). In another embodiment, the on-skin sensor control unit 44 may optionally be configured to not allow calibration or to **reject a calibration point if**, for example, 3) **the rate of change of the uncalibrated signal is above a threshold rate (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater).** (Col. 44, ll. 20-45).

3. A computer system suitable for processing analyte data, the computer system comprising:	42. A computer system suitable for processing analyte data, the computer system comprising:	(Preamble) See claim 41 above.
a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	See claim 41 above.
a processor module configured to determine a rate of change of the data stream;	a processor module configured to determine a rate of change of the data stream;	See claim 41 above.
a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	See claim 41 above.
a data matching module configured to match a reference data point to a sensor data point to form a matched data pair, wherein the reference data point and the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is	a data matching module configured to match a reference data point to a sensor data point to form a matched data pair, wherein the reference data point and the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained.	These working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16). Typically, the consecutive readings and/or the

obtained.		threshold level are determined such that all expected excursions of the sensor signal are within the desired parameters (i.e., the sensor control unit 44 does not consider true changes in analyte concentration to be a sensor failure). (Col. 39, ll. 41-46). The comparison of the two signals may be made for each measurement or at regular intervals. (Col. 39, ll. 20-21). Additionally, analyte levels, reported by the analyte monitoring device 40, may not be accurate because a **calibration of the sensor 42 has not been performed within the predetermined periodic time interval**. (Col. 44, ll. 15-19).
4. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor; a processor module configured to determine a rate of change of the data	43. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor; a processor module configured to determine a rate of change of the data	(Preamble) See claim 41 above. See claim 41 above. See claim 41 above.

stream; a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and a calibration module configured to form calibration information based at least in part on at least one reference data point and at least one sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained.	stream; a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and a calibration module configured to form calibration information based at least in part on at least one reference data point and at least one sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained.	See claim 41 above. **The processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed** and if the calibration data is acceptable. **The on-skin sensor control unit 44 may** optionally be configured to not allow calibration or to reject a calibration point if, for example … 2) **two or more working electrodes 58 provide uncalibrated signals that are not within a predetermined range** (e.g., within 10% or 20%) of each other; 3) **the rate of change of the uncalibrated signal is above a threshold rate** (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater); 4) the uncalibrated signal exceeds a threshold maximum value (e.g., 5, 10, 20, or 40 nA) or is below a threshold minimum value (e.g., 0.05, 0.2, 0.5, or 1 nA) (Col. 44, ll. 20-37). The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or**

		more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance. (Col. 39, ll. 11-16).
5. A computer system suitable for processing analyte data, the computer system comprising:	44. A computer system suitable for processing analyte data, the computer system comprising:	(Preamble) See claim 41 above.
a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	See claim 41 above.
a processor module configured to determine a rate of change of the data stream;	a processor module configured to determine a rate of change of the data stream;	See claim 41 above.
a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	See claim 41 above.
a conversion function module configured to create a conversion	a conversion function module configured to create a conversion	The processing circuit 109 may have one or more of the following functions: … 3) convert the

function based at least in part on at least one sensor data point, wherein the sensor data point is obtained when the rate of change of the data stream is below a threshold, and wherein the conversion function is configured to convert the sensor data point into a calibrated data point.	function based at least in part on at least one sensor data point, wherein the sensor data point is obtained when the rate of change of the data stream is below a threshold, and wherein the conversion function is configured to convert the sensor data point into a calibrated data point.	information-carrying characteristic of the signals from one characteristic to another (when, for example, that has not been done by the measurement circuit 96), using, for example, a current-to-voltage converter, a current-to-frequency converter, or a voltage-to-current converter, 4) **modify the signals from the sensor circuit 97 using calibration data** and/or output from the temperature probe circuit 99, 5) determine a level of an analyte in the interstitial fluid, 6) determine a level of an analyte in the bloodstream based on the sensor signals obtained from interstitial fluid, 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values,** 8) activate an alarm if a threshold value is met or exceeded, 9) evaluate trends in the level of an analyte based on a series of sensor signals (Col. 39-40, ll. 61-67, ll. 1-15). **The processing circuit 109 may also incorporate calibration data** which has been received from an external source or has been incorporated into the processing circuit 109, both of which are described below, **to correct** the signal **or analyzed data from the working electrode 58.** (Col. 40, ll. 53-58). Additionally, as shown in FIG. 24, the sensor data is displayed s a graph, thus requiring certain conversion functions, depending on the desired

		graphical output.
6. A computer system suitable for processing analyte data, the computer system comprising:	45. A computer system suitable for processing analyte data, the computer system comprising:	(Preamble) See claim 41 above.
a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	See claim 41 above.
a processor module configured to determine a rate of change of the data stream;	a processor module configured to determine a rate of change of the data stream;	See claim 41 above.
a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	See claim 41 above.
a sensor data transformation module configured to convert at least one sensor data point into a calibrated data point, wherein the rate of change of the data stream at the time at which the sensor data point is obtained is below a	a sensor data transformation module configured to convert at least one sensor data point into a calibrated data point, wherein the rate of change of the data stream at the time at which the sensor data point is obtained is below a	**The processing circuit 109 may also incorporate calibration data** which has been received from an external source or has been incorporated into the processing circuit 109, both of which are described below, **to correct** the signal **or analyzed data from the working electrode 58.**

threshold.	threshold.	(Col. 40, ll. 53-58). **The processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed** and if the calibration data is acceptable. **The on-skin sensor control unit 44 may** optionally be configured to not allow calibration or to reject a calibration point if, for example, … 3) **the rate of change of the uncalibrated signal is above a threshold rate** (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater); 4) the uncalibrated signal exceeds a threshold maximum value (e.g., 5, 10, 20, or 40 nA) or is below a threshold minimum value (e.g., 0.05, 0.2, 0.5, or 1 nA) (Col. 44, ll. 20-37).
7. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor; a processor module configured to determine a rate of change of the data	46. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor; a processor module configured to determine a rate of change of the data	(Preamble) See claim 41 above. See claim 41 above. See claim 41 above.

stream; a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; a calibration module configured to form a calibration set based at least in part on at least one matched data pair, the matched data pair comprising a reference data point and a sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times; and	stream; a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; a calibration module configured to form a calibration set based at least in part on at least one matched data pair, the matched data pair comprising a reference data point and a sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times; and	See claim 41 above. The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16). The processing circuit 109 may have one or more of the following functions: 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values.** (Col. 39-40, ll. 61-63, ll. 8-10). The comparison of the two signals may be made for each measurement or at regular intervals. (Col. 39, ll. 20-21) **The processing circuit 109 may also incorporate calibration data** which has been received from an external source or has been incorporated into the processing circuit 109, both of which are described

		below, **to correct** the signal **or analyzed data from the working electrode 58.** (Col. 40, ll. 53-58). Additionally, analyte levels, reported by the analyte monitoring device 40, may not be accurate because a **calibration of the sensor 42 has not been performed within the predetermined periodic time interval.** (Col. 44, ll. 15-19).
a calibration evaluation module configured to evaluate the matched pair, wherein the calibration evaluation module is configured to prevent the matched data pair from influencing the calibration set if the rate of change of the data stream at the time the sensor data point is obtained is above a threshold.	a calibration evaluation module configured to evaluate the matched pair, wherein the calibration evaluation module is configured to prevent the matched data pair from influencing the calibration set if the rate of change of the data stream at the time the sensor data point is obtained is above a threshold.	**The processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed** and if the calibration data is acceptable. **The on-skin sensor control unit 44 may** optionally be configured to not allow calibration or to reject a calibration point if, for example, 3) **the rate of change of the uncalibrated signal is above a threshold rate.** (Col. 44, ll. 20-34).
8. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a	47. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a	(Preamble) See claim 41 above. See claim 41 above.

plurality of time spaced sensor data points from a substantially continuous analyte sensor;	plurality of time spaced sensor data points from a substantially continuous analyte sensor;	
a processor module configured to determine a rate of change of the data stream;	a processor module configured to determine a rate of change of the data stream;	See claim 41 above.
a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	See claim 41 above.
a clinical module configured to compare a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable,	a clinical module configured to compare a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable,	The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16).
wherein the second reference data point is obtained prior to obtaining the first reference data point, and	wherein the second reference data point is obtained prior to obtaining the first reference data point, and	The processing circuit 109 may have one or more of the following functions: 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values.** (Col. 39-40, ll. 61-63, ll. 8-10).
wherein the first reference data point is determined to be clinically acceptable if the difference between the first reference data point and the second reference data point is below a threshold.	wherein the first reference data point is determined to be clinically acceptable if the difference between the first reference data point and the second reference data point is below a threshold.	An example of using signals from only one working

		electrode for quality control includes comparing consecutive readings obtained using the single working electrode to determine if they differ by more than a threshold level. (Col. 39, ll. 35-45).
9. A computer system suitable for processing analyte data, the computer system comprising:	48. A computer system suitable for processing analyte data, the computer system comprising:	(Preamble) See claim 41 above.
a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;	See claim 41 above.
a processor module configured to determine a rate of change of the data stream;	a processor module configured to determine a rate of change of the data stream;	See claim 41 above.
a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	See claim 41 above.
a clinical module configured to	a clinical module configured to	The working electrodes 58 may be used for quality

compare a first sensor data point to a second sensor data point to determine whether the first sensor data point is clinically acceptable, wherein the second sensor data point is obtained prior to obtaining the first sensor data point, and wherein the first sensor data point is determined to be clinically acceptable if the difference between the first sensor data point and the second sensor data point is below a threshold.	compare a first sensor data point to a second sensor data point to determine whether the first sensor data point is clinically acceptable, wherein the second sensor data point is obtained prior to obtaining the first sensor data point, and wherein the first sensor data point is determined to be clinically acceptable if the difference between the first sensor data point and the second sensor data point is below a threshold.	control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16). The processing circuit 109 may have one or more of the following functions: 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values.** (Col. 39-40, ll. 61-63, ll. 8-10). An example of using signals from only one working electrode for quality control includes **comparing consecutive readings** obtained using the single working electrode to determine if they differ by more than a threshold level. (Col. 39, ll. 35-45).
10. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data	49. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data	(Preamble) See claim 41 above. See claim 41 above.

points from a substantially continuous analyte sensor; a processor module configured to determine a rate of change of the data stream a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and a stability module configured to determine whether the sensor data is stable, wherein the sensor data is determined to be stable if the rate of change of the data stream is below a threshold at the time the sensor data is obtained.	points from a substantially continuous analyte sensor; a processor module configured to determine a rate of change of the data stream a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and a stability module configured to determine whether the sensor data is stable, wherein the sensor data is determined to be stable if the rate of change of the data stream is below a threshold at the time the sensor data is obtained.	 See claim 41 above. See claim 41 above. The processing circuit 109 may have one or more of the following functions: 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values**. (Col. 39-40, ll. 61-63, ll. 8-10).
11. The computer system of claim 10, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of *in vivo* glucose concentration, and **wherein the threshold is at least about 2 mg/dL/min**. 12. The computer system of claim	50. The computer system of claim 49, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of in vivo glucose concentration, and wherein **the threshold is set at a predetermined level.**	The present invention relates to devices and methods for the **in vivo monitoring of an analyte** using an electrochemical sensor to provide information to a patient about the level of the analyte (Field of Invention) The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example, … 3) **the rate of**

10, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of *in vivo* glucose concentration, and **wherein the threshold is at least about 4 mg/dL/min.**		**change of the uncalibrated signal is above a threshold rate** (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater). (Col. 44, ll. 20-35). A **threshold value is exceeded if the datapoint has a value that is beyond the threshold value** in a direction indicating a particular condition. For example, a datapoint which correlates to a glucose level of 200 mg/dL exceeds a threshold value for hyperglycemia of 180 mg/dL, because the datapoint indicates that the patient has entered a hyperglycemic state. (Col. 45, ll. 32-35).
	51. The computer system of claim 49, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of in vivo glucose concentration, and wherein the threshold is 0.25 mg/dL/min.	The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example, … 3) the rate of change of the uncalibrated signal is above a threshold rate (e.g., **0.25 mg/dL per minute** or 0.5 mg/dL per minute or greater). (Col. 44, ll. 20-35).
	52. The computer system of claim 49, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of in vivo glucose concentration, and wherein the threshold is 0.5 mg/dL/min.	The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example, … 3) the rate of change of the uncalibrated signal is above a threshold rate (e.g., 0.25 mg/dL per minute or **0.5 mg/dL per minute** or greater). (Col. 44, ll. 20-35).

	53. The computer system of claim 49, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of in vivo glucose concentration, and wherein the threshold is greater than 0.5 mg/dL/min.	The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example, … 3) the rate of change of the uncalibrated signal is above a threshold rate (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute **or greater**). (Col. 44, ll. 20-35).
13. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor; a processor module configured to determine a rate of change of the data stream; a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	54. A computer system suitable for processing analyte data, the computer system comprising: a sensor data module configured to receive sensor data, the sensor data comprising a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor; a processor module configured to determine a rate of change of the data stream; a reference input module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point; and	(Preamble) See claim 41 above. See claim 41 above. See claim 41 above. See claim 41 above.

a user interface, wherein the user interface is configured to request additional reference data when the rate of change of the data stream is above a threshold.	a user interface, wherein the user interface is configured to request additional reference data when the rate of change of the data stream is above a threshold.	The processing circuit 109 or an analyzer 152 **may also request another calibration point if the values determined using the sensor data before and after the latest calibration disagree by more than a threshold amount**, indicating that the calibration may be incorrect or that the sensor characteristics have changed radically between calibrations. This additional calibration point may indicate the source of the difference. (Col. 44, ll. 46-53).
14. A device for monitoring glucose concentration in a biological sample of a host, the device comprising:	55. A device for monitoring glucose concentration in a biological sample of a host, the device comprising:	(Preamble) The present invention relates to devices and methods for the in vivo monitoring of an analyte using an electrochemical sensor to provide information to a patient about the level of the analyte. (Field of Invention)
a substantially continuous glucose sensor that produces a data stream indicative of a glucose concentration in a host, the data stream comprising a plurality of time spaced sensor data points;	a substantially continuous glucose sensor that produces a data stream indicative of a glucose concentration in a host, the data stream comprising a plurality of time spaced sensor data points;	The on-skin sensor control unit 44 also typically includes at least a portion of the electronic components that operate the sensor 42 and the analyte monitoring device system 40. One embodiment of the electronics in the on-skin control unit 44 is illustrated as a block diagram in FIG. 18A. The electronic components of the on-skin sensor control unit 44 typically include a power supply 95 for operating the on-skin control unit 44 and the sensor 42, **a sensor circuit 97 for obtaining signals from and operating the sensor 42**, a measurement

		circuit 96 that converts sensor signals to a desired format, and **a processing circuit 109 that, at minimum, obtains signals from the sensor circuit 97** and/or measurement circuit 96 and provides the signals to an optional transmitter 98. (Col. 36, ll. 41-60). The processing circuit 109 may have one or more of the following functions: 5) determine a level of an analyte in the interstitial fluid, 6) determine a level of an analyte in the bloodstream based on the sensor signals obtained from interstitial fluid, **7) determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values**, (Col. 39-40, ll. 61-62 and 5-10). Additionally: Typically, **data is transmitted to the receiver/display unit 46, 48 at least every hour, preferably, at least every fifteen minutes, more preferably, at least every five minutes, and most preferably, at least every one minute**. (Col. 43, ll. 9-12).
an integrated receiver that receives the data stream from the substantially continuous glucose sensor, wherein the integrated receiver comprises:	an integrated receiver that receives the data stream from the substantially continuous glucose sensor, wherein the integrated receiver comprises:	The on-skin sensor control unit 44 also typically includes at least a portion of the electronic components that operate the sensor 42 and the analyte monitoring device system 40. The electronic components of the on-skin sensor control unit 44 typically include a power supply 95 for operating the

		on-skin control unit 44 and the sensor 42, **a sensor circuit 97 for obtaining signals from and operating the sensor 42.** (Col. 36, ll. 39-50).
a single point glucose monitor configured to receive a biological sample from the host and to measure the concentration of glucose in the sample, the measured glucose concentration comprising a reference data point;	a single point glucose monitor configured to receive a biological sample from the host and to measure the concentration of glucose in the sample, the measured glucose concentration comprising a reference data point;	The electronic components of the on-skin sensor control unit 44 typically include a power supply 95 for operating the on-skin control unit 44 and the sensor 42, **a sensor circuit 97 for obtaining signals from and operating the sensor 42**, a measurement circuit 96 that converts sensor signals to a desired format, and **a processing circuit 109 that, at minimum, obtains signals from the sensor circuit 97** (Col. 36, ll. 41-53). The processing circuit 109 may have one or more of the following functions: 5) determine a level of an analyte in the interstitial fluid, 6) determine a level of an analyte in the bloodstream based on the sensor signals obtained from interstitial fluid, **7) determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values,** (Col. 39-40, ll. 61-62 and 5-10). In another embodiment, calibration data may be obtained in a variety of ways. For instance, the calibration data may simply be factory-determined calibration measurements which can be input into

		the on-skin sensor control unit 44 using the receiver 99 or may alternatively be stored in a calibration data storage unit 100 within the on-skin sensor control unit 44 itself (in which case a receiver 99 may not be needed). The calibration data storage unit 100 may be, for example, a readable or readable/writeable memory circuit. Alternative or additional calibration data may be provided based on tests performed by a doctor or some other professional or by the patient himself. For example, **it is common for diabetic individuals to determine their own blood glucose concentration using commercially available testing kits.** The results of this test is input into the on-skin sensor control unit 44 either directly. (Col. 43, ll. 36-48).
a microprocessor; and a computer readable memory comprising:	a microprocessor; and a computer readable memory comprising:	The processing circuit 109 often includes digital logic circuitry. (Col. 39, ll. 59-60).
instructions configured to cause the microprocessor to process the data stream received from the continuous glucose sensor; instructions configured to cause the microprocessor to determine a rate of change of the data stream from	instructions configured to cause the microprocessor to process the data stream received from the continuous glucose sensor; instructions configured to cause the microprocessor to determine a rate of change of the data stream from the	The processing circuit 109 may have one or more of the following functions: 5) determine a level of an analyte in the interstitial fluid, 6) determine a level of an analyte in the bloodstream based on the sensor signals obtained from interstitial fluid, **7) determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values**, (Col. 39-40, ll. 61-

the substantially continuous analyte sensor; and instructions configured to cause the microprocessor to calibrate the data stream using the glucose concentration measured by the single point glucose monitor.	substantially continuous analyte sensor; and instructions configured to cause the microprocessor to calibrate the data stream using the glucose concentration measured by the single point glucose monitor.	62 and 5-10). Other methods of independently determining analyte levels may also be used to obtain calibration data. (Col. 43, ll. 58-59). The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16).
15. The device of claim 14, wherein the reference input module is configured to reject a reference data point obtained when the rate of change of the data stream is above a threshold. **[Note: No antecedent basis in Claim 15 of the '876 Application for "reference input module"]**	56. The device of claim 55, further comprising a reference input module configured to reject a reference data point obtained when the rate of change of the data stream is above a threshold.	The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance. ...** Moreover, the signals from both sensors may be used to generate data or **one signal may be discarded after the comparison.** (Col. 39, ll. 11-25). **The processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the**

		receiver/display unit 46, 48 may determine when calibration data is needed and if the calibration data is acceptable. **The on-skin sensor control unit 44 may** optionally be configured to not allow calibration or to reject a calibration point if, for example, 3) **the rate of change of the uncalibrated signal is above a threshold rate.** In another embodiment, the on-skin sensor control unit 44 may optionally be configured to not allow calibration or to **reject a calibration point if**, for example, 3) **the rate of change of the uncalibrated signal is above a threshold rate (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater).** (Col. 44, ll. 20-45).
16. The device of claim 14, further comprising a data matching module configured to match a reference data point to a sensor data point to form a matched data pair, wherein the reference data point and	57. The device of claim 55, further comprising a data matching module configured to match a reference data point to a sensor data point to form a matched data pair, wherein the reference data point and	See claim 55. The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16). The comparison of the two signals may be made for

the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained.	the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained.	each measurement or at regular intervals. (Col. 39, ll. 20-21).
17. The device of claim 14, further comprising a calibration module configured to form calibration information based at least in part on at least one reference data point and at least one sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained.	58. The device of claim 55, further comprising a calibration module configured to form calibration information based at least in part on at least one reference data point and at least one sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times, and wherein the rate of change of the data stream is below a threshold at the time the sensor data point is obtained.	See claim 55. **The processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed** and if the calibration data is acceptable. **The on-skin sensor control unit 44 may** optionally be configured to not allow calibration or to reject a calibration point if, for example, 1) a temperature reading from the temperature probe indicates a temperature that is not within a predetermined acceptable range (e.g., 30 to 42.degree. C. or 32 to 40.degree. C.) or that is changing rapidly (for example, 0.2.degree. C./minute, 0.5.degree. C./minute, or 0.7.degree. C./minute or greater); 2) two or more working electrodes 58 provide uncalibrated signals that are not within a predetermined range(e.g., within 10% or 20%) of each other; 3) **the rate of change of the uncalibrated signal is above a threshold rate** (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater); 4) the uncalibrated signal exceeds a threshold maximum value (e.g., 5, 10, 20, or 40 nA)

		or is below a threshold minimum value (e.g., 0.05, 0.2, 0.5, or 1 nA) (Col. 44, ll. 20-37). The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16). Additionally, analyte levels, reported by the analyte monitoring device 40, may not be accurate because a **calibration of the sensor 42 has not been performed within the predetermined periodic time interval.** (Col. 44, ll. 15-19).
18. The device of claim 14, further comprising a conversion function module configured to create a conversion function based at least in part on at least one sensor data point, wherein the sensor data point is obtained when the rate of change of the data stream is below a threshold, and	59. The device of claim 55, further comprising a conversion function module configured to create a conversion function based at least in part on at least one sensor data point, wherein the sensor data point is obtained when the rate of change of the data stream is below a threshold, and	See claim 55. The processing circuit 109 may have one or more of the following functions: … 3) convert the information-carrying characteristic of the signals from one characteristic to another (when, for example, that has not been done by the measurement circuit 96), using, for example, a current-to-voltage converter, a current-to-frequency converter, or a voltage-to-current converter, 4) **modify the signals**

wherein the conversion function is configured to convert the sensor data point into a calibrated data point.	wherein the conversion function is configured to convert the sensor data point into a calibrated data point.	**from the sensor circuit 97 using calibration data** and/or output from the temperature probe circuit 99, 5) determine a level of an analyte in the interstitial fluid, 6) determine a level of an analyte in the bloodstream based on the sensor signals obtained from interstitial fluid, 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values,** 8) activate an alarm if a threshold value is met or exceeded, 9) evaluate trends in the level of an analyte based on a series of sensor signals (Col. 39-40, ll. 61-67, ll. 1-15). **The processing circuit 109 may also incorporate calibration data** which has been received from an external source or has been incorporated into the processing circuit 109, both of which are described below, **to correct** the signal **or analyzed data from the working electrode 58.** (Col. 40, ll. 53-58).
19. The device of claim 14, further comprising a sensor data transformation module configured to convert at least one sensor data point into a calibrated data point, wherein the rate of change of the data stream at the time at which the	60. The device of claim 55, further comprising a sensor data transformation module configured to convert at least one sensor data point into a calibrated data point, wherein the rate of change of the data stream at the time at which the sensor	See claim 55. **The processing circuit 109 may also incorporate calibration data** which has been received from an external source or has been incorporated into the processing circuit 109, both of which are described below, **to correct** the signal **or analyzed data from**

sensor data point is obtained is below a threshold.	data point is obtained is below a threshold.	**the working electrode 58.** (Col. 40, ll. 53-58). **The processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed** and if the calibration data is acceptable. **The on-skin sensor control unit 44 may** optionally be configured to not allow calibration or to reject a calibration point if, for example, 1) a temperature reading from the temperature probe indicates a temperature that is not within a predetermined acceptable range (e.g., 30 to 42.degree. C. or 32 to 40.degree. C.) or that is changing rapidly (for example, 0.2.degree. C./minute, 0.5.degree. C./minute, or 0.7.degree. C./minute or greater); 2) two or more working electrodes 58 provide uncalibrated signals that are not within a predetermined range(e.g., within 10% or 20%) of each other; 3) **the rate of change of the uncalibrated signal is above a threshold rate** (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater); 4) the uncalibrated signal exceeds a threshold maximum value (e.g., 5, 10, 20, or 40 nA) or is below a threshold minimum value (e.g., 0.05, 0.2, 0.5, or 1 nA) (Col. 44, ll. 20-37).
20. The device of claim 14, further comprising:	61. The device of claim 55, further comprising:	

a calibration module configured to form a calibration set based at least in part on at least one matched data pair, the matched data pair comprising a reference data point and a sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times; and	a calibration module configured to form a calibration set based at least in part on at least one matched data pair, the matched data pair comprising a reference data point and a sensor data point, wherein the reference data point and the sensor data point are obtained at substantially corresponding times; and	The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16). The processing circuit 109 may have one or more of the following functions: 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values.** (Col. 39-40, ll. 61-63, ll. 8-10). **The processing circuit 109 may also incorporate calibration data** which has been received from an external source or has been incorporated into the processing circuit 109, both of which are described below, **to correct** the signal **or analyzed data from the working electrode 58.** (Col. 40, ll. 53-58). Additionally, analyte levels, reported by the analyte monitoring device 40, may not be accurate because a **calibration of the sensor 42 has not been performed within the predetermined periodic time interval.** (Col. 44, ll. 15-19).

a calibration evaluation module configured to evaluate the matched pair, wherein the calibration evaluation module is configured to prevent the matched data pair from influencing the calibration set if the rate of change of the data stream at the time the sensor data point is obtained is above a threshold.	a calibration evaluation module configured to evaluate the matched pair, wherein the calibration evaluation module is configured to prevent the matched data pair from influencing the calibration set if the rate of change of the data stream at the time the sensor data point is obtained is above a threshold.	**The processing circuit 109 of the on-skin sensor control unit 44 and/or an analyzer 152 of the receiver/display unit 46, 48 may determine when calibration data is needed** and if the calibration data is acceptable. **The on-skin sensor control unit 44 may** optionally be configured to not allow calibration or to reject a calibration point if, for example, 3) **the rate of change of the uncalibrated signal is above a threshold rate.** (Col. 44, ll. 20-34).
21. The device of claim 14, further comprising a clinical module configured to compare a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable, wherein the second reference data point is obtained prior to obtaining the first reference data point, and wherein the first reference data point is determined to be clinically acceptable if the difference between the	62. The device of claim 55, further comprising a clinical module configured to compare a first reference data point to a second reference data point to determine whether the first reference data point is clinically acceptable, wherein the second reference data point is obtained prior to obtaining the first reference data point, and wherein the first reference data point is determined to be clinically acceptable if the difference between the first	See claim 55. The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16). The processing circuit 109 may have one or more of the following functions: 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values.**

first reference data point and the second reference data point is below a threshold.	reference data point and the second reference data point is below a threshold.	(Col. 39-40, ll. 61-63, ll. 8-10). An example of using signals from only one working electrode for quality control includes comparing consecutive readings obtained using the single working electrode to determine if they differ by more than a threshold level. (Col. 39, ll. 34-40).
22. The device of claim 14, further comprising a clinical module configured to compare a first sensor data point to a second sensor data point to determine whether the first sensor data point is clinically acceptable, wherein the second sensor data point is obtained prior to obtaining the first sensor data point, and wherein the first sensor data point is determined to be clinically acceptable if the difference between the first sensor data point and the second sensor data point is below a threshold.	63. The device of claim 55, further comprising a clinical module configured to compare a first sensor data point to a second sensor data point to determine whether the first sensor data point is clinically acceptable, wherein the second sensor data point is obtained prior to obtaining the first sensor data point, and wherein the first sensor data point is determined to be clinically acceptable if the difference between the first sensor data point and the second sensor data point is below a threshold.	See claim 55. The working electrodes 58 may be used for quality control purposes. For example, the **output signals and/or analyzed data derived using the two or more working electrodes 58 may be compared to determine if the signals from the working electrodes agree within a desired level of tolerance.** (Col. 39, ll. 11-16). The processing circuit 109 may have one or more of the following functions: 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values.** (Col. 39-40, ll. 61-63, ll. 8-10). An example of using signals from only one working electrode for quality control includes comparing consecutive readings obtained using the single

		working electrode to determine if they differ by more than a threshold level. (Col. 39, ll. 34-40).
23. The device of claim 14, further comprising a stability module configured to determine whether the sensor data is stable, wherein the sensor data is determined to be stable if the rate of change of the data stream is below a threshold at the time the sensor data is obtained.	64. The device of claim 55, further comprising a stability module configured to determine whether the sensor data is stable, wherein the sensor data is determined to be stable if the rate of change of the data stream is below a threshold at the time the sensor data is obtained.	See claim 55. The processing circuit 109 may have one or more of the following functions: 7) **determine if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values.** (Col. 39-40, ll. 61-63, ll. 8-10).
24. The device of claim 23, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of *in vivo* glucose concentration, and **wherein the predetermined threshold is at least about 2 mg/dL/min**. 25. The device of claim 23, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of *in vivo*	65. The device of claim 64, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of in vivo glucose concentration, and wherein **the threshold is set at a predetermined level.**	The present invention relates to devices and methods for the **in vivo monitoring of an analyte** using an electrochemical sensor to provide information to a patient about the level of the analyte (Field of Invention) The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example, … 3) **the rate of change of the uncalibrated signal is above a threshold rate** (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or greater). (Col. 44, ll. 20-35).

glucose concentration, and **wherein the predetermined threshold is at least about 4 mg/dL/min.**		A **threshold value is exceeded if the datapoint has a value that is beyond the threshold value** in a direction indicating a particular condition. For example, a datapoint which correlates to a glucose level of 200 mg/dL exceeds a threshold value for hyperglycemia of 180 mg/dL, because the datapoint indicates that the patient has entered a hyperglycemic state. (Col. 45, ll. 32-35).
	66. The device of claim 64, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of in vivo glucose concentration, and wherein the threshold is 0.25 mg/dL/min.	The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example, … 3) the rate of change of the uncalibrated signal is above a threshold rate (e.g., **0.25 mg/dL per minute** or 0.5 mg/dL per minute or greater). (Col. 44, ll. 20-35).
	67. The device of claim 64, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of in vivo glucose concentration, and wherein the threshold is 0.5 mg/dL/min.	The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example, … 3) the rate of change of the uncalibrated signal is above a threshold rate (e.g., 0.25 mg/dL per minute or **0.5 mg/dL per minute** or greater). (Col. 44, ll. 20-35).
	68. The device of claim 64, wherein the analyte comprises glucose, wherein the data stream comprises measurements indicative of in vivo glucose	The on-skin sensor control unit 44 may optionally be configured to not allow calibration or to reject a calibration point if, for example, … 3) the rate of change of the uncalibrated signal is above a

	concentration, and wherein the threshold is greater than 0.5 mg/dL/min.	threshold rate (e.g., 0.25 mg/dL per minute or 0.5 mg/dL per minute or **greater**). (Col. 44, ll. 20-35).
26. The device of claim 14, further comprising a user interface, wherein the user interface is configured to request additional reference data when the rate of change of the data stream is above a predetermined threshold.	69. The device of claim 55, further comprising a user interface, wherein the user interface is configured to request additional reference data when the rate of change of the data stream is above a predetermined threshold.	The processing circuit 109 or an analyzer 152 **may also request another calibration point if the values determined using the sensor data before and after the latest calibration disagree by more than a threshold amount**, indicating that the calibration may be incorrect or that the sensor characteristics have changed radically between calibrations. This additional calibration point may indicate the source of the difference. (Col. 44, ll. 46-53).